



Searching for a Cure: The FDA's Regulatory Approach to Traditional Chinese Herbal Medicine

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Searching for a Cure:

The FDA's Regulatory Approach to Traditional Chinese Herbal Medicine

Submitted to Professor Peter Barton Hutt in the Seminar on Food and Drug
Law in

Satisfaction of the Written Work Requirement.

AnnaL. Kim

May 1, 1997

Traditional Chinese herbal medicine has recently enjoyed a dramatic increase in popularity in the United States, however, currently, it is not specifically regulated by the Food and Drug Administration (FDA). The FDA policy towards Chinese herbal medicine at the present time is one of non-action until complaints about a product are filed, at which point the FDA can then decide to take certain steps within its enforcement powers, including issuing warning letters and import alerts, removing the product from the market through seizures, and prosecuting the manufacturers. Nevertheless, this wait-and-see policy allows both imported and domestically produced Chinese herbal medicines to float freely in Asian shops as well as in general health food stores without FDA oversight, at least until complaints are lodged. This is troublesome because there are real and present dangers involved with the use of Chinese herbal medicines that militate for a more proactive role to be undertaken by the FDA. I will begin this discussion by describing traditional Chinese medicine and how it compares to the Western medical tradition. Second, I will then examine why regulation is necessary given the impact of Chinese herbal medicine on American health-care. Then, I will proceed to the problem of trying to fit a square peg into a round hole, namely, the issue of regulating Chinese herbal medicine under current statutory provisions. Fourth, I will analyze state and federal responses to alternative therapies in general and Chinese herbal medicine in particular, afterwards focusing on the FDA's piecemeal approach thus far. Finally, I will examine two potential models for reform, Germany and Canada, to see if there are lessons to be learned from their practices.

I. Introduction to Traditional Chinese Medicine

A. Traditional Chinese Medicine: A Brief History

The beginning of documented Chinese medicine can be traced to fourteen manuscripts on various aspects of health care dating back to 167 B.C., discovered in an excavated tomb at the Ma-wang-tui site in Hunan province in 1972.¹ Pharmaceutical knowledge was first found recorded in the Ma-wang-mi scripts, in a work known as *Pr̃ripli~n~ Against 52 Ailments* (*Wu-shih-erh ping fang*) and chronicled a significant shift in our

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understanding of the Chinese approach to illness and disease. The manuscripts signaled

an important turning point: the incipient development of a system of health care beliefs and practices that shifted away from a metaphysical emphasis on an individual's

interactions with his ancestors towards a greater emphasis on the concrete illnesses of the

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human mind and body. Up to this time, approximately the second century B.C., a

person's health was thought to depend upon interactions with one's ancestors.⁴ Following certain norms of conduct was believed to assure health and well-being, while a failure to do so incited the wrath of the dead ancestors, which could manifest itself in the form of disease and illness.⁵ The ancestral spirits had to then be appeased with sacrifices.⁶

¹Paul Unschuld, *History of Chinese Medicine*, in The Cambridge World History of Human Di~a~, at 21 (Kenneth Kiple ed., 1983).

² Id. at 21.

³ Id. at 20.

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By the first century, various divergent schools of medical thought had emerged, and were compiled in the classic text that has profoundly shaped Chinese medical thought, The Yellow Emperor's Classic of Internal Medicine, (*Huang-ti nei-ching*)⁹ Traditional Chinese medical treatment, with roots dating back millennia, is premised on the concept that the human body is a unified organic entity, a microcosm of the socioeconomic structure of the Chinese empire, with different units performing its own tasks and channeling resources from the outside and those developed from within

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throughout the body. The resources distributed throughout the body were designated as *ch'i* in The Yellow Emperor's Classic of Internal Medicine, and referred to vital vapors

essential to the organism's existence.⁹ The invisible *dz'i*, or vital energy, circulates through a system of conduits, the principal ones being the meridians or channels, as well as through the blood.¹⁰ This idea echoes analogous early European concepts, such as the *spiritus*, and both may have originated from observations of phenomena such as

suffocation and empty vessels (i.e. arteries, derived from *aer tereo*, carriers of air) in

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a corpse.

Like all medicine, the purpose of Chinese medicine is health, and in The Yellow Emperor's Classic of Internal Medicine, a generally healthy person who lived a

Id. The precise date of composition and authorship of The Yellow Emperor's Classic of Internal Medicine is a subject of debate. —8 of Traditional Chinese Medicine. Vol. 2: Clinical E.g., Liu Yangchi, The Essential Book

Pratk at 1 (Fang Tingyu and Chen Laidi trans., 1988); ~nlsQ, Unschuld, supra note 1, at 21.

10 Ralph Alan Dale, The Forms of Qi (Vital Energy) in Acupuncture, American Journal of

A~upun~fl~r~

Vol. 22, (1994).

Unschuld, supra note 1, at 21.

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temperate life was believed to have a life span of one hundred years. The work explicitly acknowledged that lifestyle was a factor in a person's health and longevity.¹³ As a result, there is an emphasis in The Yellow Emperor's Classic of Internal Medicine on preventive medicine.¹⁴ This emphasis on prevention is also implied in the first Chinese exclusively herbal work, generally agreed to have been compiled in the first century, Shen-nung-ko-ts'ung ching.¹⁵ In The Divine Husbandman's Classic on Materia Medica, the legendary sage Shen Nung is depicted as an experimentalist who tasted different plants and classified them according

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to their nature and their effects for medicinal purposes. The 365 plants described in the

work are divided into three categories, superior, medium, and inferior, determined by their rejuvenating, tonic, or curative properties.¹⁷ Since the rejuvenating plants were

deemed the superior, this suggests again that prevention was more highly regarded than

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curing in traditional Chinese medicine.

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The Yellow Emperor's Classic of Internal Medicine, supra note 2, at 97-98.

13 The author states that the ancients were able to live past one hundred years of age because [t]here was temperance in eating and drinking. Their hours of rising and retiring were regular and not disorderly and wild. Id. at 97.

14 In the work, the author comments To administer medicines to diseases which have already developed and to suppress revolts which have already developed is comparable to the behavior of those persons who begin to dig a well after they have become thirsty, and of those who begin to cast weapons after they have already engaged in battle. Would these actions not be too late? Id. at 105.

15 Id. Here again, the exact date and authorship is unclear. Id.

16

Lu Gwei-Djen & Joseph Needham, A Contribution to the History of Chinese Dietetics, in Science & Technology in East Asia at 86 (Nathan Sivin, ed., 1977).

¹⁷Id.

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Id. Interestingly, Lu and Needham believe that credit for the discovery of the importance of diet and its relation to certain deficiency diseases should be given to Chinese civilization. Id. at

91.

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There is a dichotomy in the methods of treatment found in traditional Chinese medicine, which can be characterized as the medicines of systematic correspondence, and

that of pragmatic drug therapy.¹⁹ The dichotomy may be a result of the rivalry between

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the Confucian-Legalist school and the Taoist worldview. The Confucian-Legalists

believed in a social order maintained by appropriate legal and moral behavior, hence they

encouraged medicine based on systematic correspondence, which promised health to

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those who followed a correct lifestyle. Pharmaceutical relief, however, was obtainable

by anyone, regardless of their lifestyle or morality, and so was more closely tied to Taoism, which rejected the rigidity of Confucian standards of behavior and thought.²² The philosophy of systematic correspondence held that there was a relationship between all things in the universe, which could be placed into two (*yin-yang*) or five (five phases)

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categories for all phenomena. The *yin-yang* school assumes an antagonistic unity

between the different entities in the universe, e.g. day and night, male and female, heaven

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and earth. Around the fourth century B.C., certain terms including day, male, and

heaven, were deemed qualitatively identical and described as *yang*, while their opposites,

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night, female, earth, were called *yin*. The five phases school identified five groupings

of qualitatively identical phenomena symbolized by five elements: metal, wood, water, fire, and soil, which also was thought to correspond to the five major organs of the body:

¹⁹ Unschuld, *supra* note 1, at 23.

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

Id. at 24.

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²⁵ *Id.*

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lungs (metal), liver (wood), kidneys (water), heart (fire), spleen (soil). On the other

hand, The Divine Husbandman's Classic on Materia Medica contained almost no

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reference to systematic correspondence. Traditional Chinese pharmaceuticals grew from

the 365 substances documented in The Divine Husbandman's Classic on Materia Medica to 850 compounds in the first government-backed collection of herbal substances in 659,

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to the over 1,700 drug descriptions published from 960 to 1126. When the seminal text,

~ (arranged according to drug descriptions and technical aspects), (~z t, ~j~angizw), was published in 1596 by Li Shih-chen, it boasted more than 1,800 drug

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monographs and more than 11,000 prescriptions in 52 volumes. The break between the

two major traditions of Chinese medicine, systematic correspondence and pragmatic therapy, was closed by the thirteenth century, however, when scholars such as K'ou

Tsung-shih, Chang Yuan-su, and Wang Haogu, began developing a pharmacology based

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on systematic correspondence. Chinese herbal pharmacology was henceforth classified

based on the philosophy of systematic correspondence.

B. Traditional Chinese Medicine: Definitions

Traditional Chinese medicine refers to a health care system with an array of treatment options besides herbal medicine, including acupuncture, moxibustion, Tui Na, Tai Chi, Qui Gong, which will be addressed briefly. Acupuncture is first referred to in Chinese literature in 90 B.C., but its origins are unclear.³¹ It may have arisen from

26 The Yellow Emperor's Classic of Internal Medicine, supra note 7, at 21.

27 Unschuld, supra note 1 at 21.

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14. at 25.

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31 Id.at 23.

attempts to pierce regions of the body thought to be overrun by some kind of outside evil

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with symbolic swords. Acupuncture made its widespread debut in the U.S. in 1971, when James Reston reported in the New York Times how physicians in Beijing had

alleviated his post-surgery abdominal pains with acupuncture?~ Acupuncture has won adherents for its usefulness in helping to ease chronic pain, arthritis, post-surgery nausea, migraines and fatigue.³⁴ It has been reported that an estimated 15 million Americans have tried acupuncture. In 1993 the FDA declared that Americans spent \$500 million a

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year on an estimated 9 million to 12 million visits for acupuncture therapy. Thirty

states have legalized acupuncture and more than 20 acupuncture schools have been accredited by the U.S. Department of Education.³⁷ In March 1996, the FDA classified acupuncture needles as class II medical devices, removing a major barrier to insurance coverage, although it is still too early to know with certainty whether this ruling will

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automatically qualify acupuncture treatments for insurance coverage. Under the new classification, as with other class II medical devices, the needles are required to have

proper labeling and good manufacturing practices.³⁹ Needle manufacturers will have to submit documents regarding the materials used and the needles are required to have prescription labels restricting use to qualified practitioners as determined by individual

32 Id. at 21.

Caryle Murphy, Acupuncture Boom: Eastern Technique Is Growing In Popularity But

Western Scientists Look for More Proof, The Washington Post, October 8, 1996.

³⁴Id.

~ Rick Weiss, Los Angeles Times, March 30, 1996, at A-16.

36 Murphy, *supra* note 33.

37Id.

38 EDA&Qnsu1n~r, June 1996, at 4; s~aJsu Weiss, *supra* note 35.

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states. Although this discussion focuses on Chinese herbal medicines, acupuncturists often prescribe Chinese herbal medicines as part of their treatment, so there is a noteworthy relationship between the acceptance of acupuncture and that of Chinese herbal medicine. Moxibustion, another form of therapy with theoretical underpinnings similar to those underlying acupuncture, involves applying combustible cones of powdered leaves of *Artemisia vulgaris* (mugwort) to the skin.⁴¹ These cones are ignited on specific locations on the body and left to burn until a blister is formed.⁴² Tui Na, another type of therapy, is a form of massage used to treat muscle injuries.⁴³ Finally, there are Tai Qi and Qui Gong, which are types of exercise that apply principles of

traditional Chinese philosophy to strengthen the body and increase a person's level of

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energy. All of these forms of therapy can and are used in conjunction with Chinese herbal medicine.

C. Traditional Classification of Chinese Medicinal Herbs: An Overview

Chinese medicinal herbs, which include plant, animal, and mineral products, all have properties and flavors which are considered together in deciding a course of

treatment.⁴⁵ The properties of herbs refer to the sorts of conditions they treat, developed

through centuries of use. The flavor of the herbs originated from its taste, when people long ago tasted them, since in ancient times there was no way to classify them by

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41 The Yellow Emperor's Classic of Internal Medicine, supra note 7, at 58-9.

Id. at 59.

42 Website of the American College of Traditional Medicine.

Id.

43 Yanchi, supra note 8, at 43-44.

46 Id. at 44.

chemical composition.⁴⁷ Each medicinal herb has one of four properties depending on its

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therapeutic effects: cold, hot, warm, or cool. Hot differs from warm and cold differs from cool only in degree, and within each category, various degrees exist as well.⁴⁹

Those herbs that effectively treat heat symptom-complexes, such as fevers and sore throat, are deemed to possess cool or cold properties, while those that are effective against cold symptom-complexes, such as pathogenic colds or a weak pulse, are said to have warm or hot properties.⁵⁰ There are also five basic flavors medicinal herbs possess:

pungent, sweet, sour, bitter, and salty.⁵¹ Also, some herbs are said to be insipid (lacking

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in flavor), or to cause a puckery sensation. The five flavors are believed to correspond

to the five elements and the five major organs.⁵³ Pungent herbs have a dispersing action, and promote energy and blood flow, working primarily in the lung and large intestine. Sweet herbs are tonics and regulate the functions of the spleen and stomach. Sour herbs

are astringents and stop discharges and diarrhea, effective primarily in the liver and

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gallbladder. Puckery herbs have effects similar to sour herbs, and are used to treat

urinary frequency and bleeding.⁵⁷ Bitter herbs are used to treat the heart and small

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intestine, and are generally good for constipation and restlessness due to heat. Salty

herbs reduces swelling and relieves constipation, and are effective in treating the kidney

⁴⁷1d.

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⁴⁹1d.

⁵⁰1d.

⁵¹1d.

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⁵³1d.at45.

⁵⁴1d.

Id.

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⁵⁷1d.

and urinary bladder.⁵⁹ Insipid herbs treat conditions of dampness, and are used to treat

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edema and trouble with urination.

Each herb is also classified as one or more of the following: ascending,

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descending, floating, and sinking. Ascending and descending refers to the direction of the activity, and floating herbs disperse pathogenic factors while sinking herbs have

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tranquilizing effects. Herbs with ascending and floating characteristics are used to energize, dispel pathogenic wind and cold, induce vomiting, and to resuscitate.⁶³ The

functions of herbs with descending and sinking tendencies include promoting the removal of waste from the bowels, dispelling heat, tranquilizing nerves, checking the profusion of

vital functions, aiding digestion, and relieving cough and asthma.⁴ Most ascending and

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floating herbs are pungent or sweet in flavor, and have warm or hot properties.

Descending or sinking herbs tend to be sour, bitter, salty or puckery, and have cold or

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cool properties.

Precautions are taken by Chinese herbal practitioners when prescribing medicinal

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herbs, as certain herbs are known to have drastic or toxic effects. For example, certain herbs should not be prescribed to women who are pregnant because they are known to

induce abortion, such as *Fructus Crotonis*, (croton fruit), *Moschus* (musk), *Hirudo*

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591d.

60~

61 Id. at46.

63~

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671d.at47.

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⁶⁸1d.at48.

⁶⁹ Unschuld, *supra* note 1, at 24.

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(leech), and *Tabanus Bivittatus* (*gadfly*). Certain dietary prohibitions also apply when particular herbs are being taken as they might counteract the medicine, and it is generally recommended that raw, cold, greasy and irritant foods should be eschewed when taking herbal medicines.⁶⁸

D. Western Medical Tradition Compared

To say that traditional Chinese medicine has progressed is, strictly speaking, somewhat of a mischaracterization. Notions of progress often implies that something was left behind, and with traditional Chinese medicine this was simply not the case.⁶⁹ Medical knowledge was expanded upon with few changes, as with the growth in pharmaceutical literature, which saw little change except for certain herbals being

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characterized as no longer in use. Major paradigm shifts did not occur in traditional

Chinese medical science as it did in the West, but this is not to say that traditional Chinese medical therapies should be rejected on the basis of its failing to conform with Western scientific sensibilities. Indeed, Western science made its greatest advances through its adherence to the Baconian scientific method, but one of the results has been a legacy of distrust and disdain towards knowledge gleaned without the benefit of scientific experiments and careful controls. In traditional Chinese pharmaceutical medicine, an assortment of plants, animals, and minerals is made into a mixture to treat a specific individual. This kind of tailoring of treatment is troublesome to most Western practitioners, who believe that dosages should generally be relatively uniform and who

are fixated with determining the specific effect of each constituent ingredient.⁷¹ Disease is viewed as separate from the person in Western medicine, whereas in Chinese medicine, the two are not so unyieldingly demarcated.

II. Is Regulation of Traditional Chinese Herbal Medicine Necessary?

A. A Study of Five Sample Products

Chinese herbal medicines can be gotten in three forms: i) some herbs are available at local Chinese markets and are used in recipes for simple herbal remedies, acquired

through family and friends; ii) more complex formulas can be procured at herbal stores

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and pharmacies. The herbal prescription is usually drawn up by an herbal practitioner

and formulated to specifically match the individual's diagnosis, and the prescription is then filled by the pharmacist who weighs out the correct amount of herbs.⁷³ At some shops, the pharmacist both prescribes and dispenses the remedy to the individual.⁷⁴ The third means by which Chinese herbal remedies are obtained is through imported prepackaged herbal medicines, also known as Chinese patent medicines, and sold in pill,

⁷¹ e.g., Herbal Pharmacology in the People's Republic of China: A Trip Report of the American Herbal Pharmacology Delegation, National Academy of Sciences, at 7 (1975). Perhaps this basic difference between traditional Chinese and Western medicine stems from divergent views of the world. Nathan Sivin has suggested that the gradual acceptance in the West of the idea of a mechanical universe with its accompanying notions of causality played a part in the differing outlooks between traditional Chinese and Western medicine. These mechanistic ideas played a negligible role in traditional Chinese culture and medicine, which were shaped by ideas of *yin-yang*, five phases, and other related concepts. Science and Technology in East Asia, supra note 16 at xix.

⁷²

Linda Barnes, Alternative Pursuits: A History of Chinese Healing Practices in the Context of American Religions and Medicines, with an Ethnographic Focus on the City of Boston 428 ~1995) (Unpublished Ph.D. dissertation, Harvard University).

Id. at 429.

⁷⁴ Id.

capsule or tonic form.⁷⁵ The imported prepackaged medicines make a range of claims:

from alleviating coughs and colds to treating the most serious of diseases. The following are five samples of Chinese herbal medicines readily available for purchase:⁷⁶

1. *Fare-You (Vitamin U complex)*. (50 tablets) The latest and most effective remedy for various sorts of gastric pains, and ulcer and duodenal ulcers. Qiaoguang Pharmaceutical Factory, Guangzhou, China.

Indication: Treatment of peptic ulcers: as gastric and duodenal ulcers, achylia gastrica, hyperacidity, chronic gastritis, regurgitativa and lesions in the coats of the stomach. *Dosage*: 1-2 tablets each time, Thrice a day.

The insert stated in English and Chinese:

Description:

The preparation of FARE-YOU (Vitamin U complex) is a new special remedy. They are made from the best quality of vitamin U and other ingredients. These tablets are reputed to be the latest and the most effective medicine for gastric and duodenal ulcers, chronic gastritis and various types of gastropathies. The disease mentioned above generally are due to the functional irritation of the gaster or lesions in the coats of the stomach. But nothing can resolve the difficulties of the problem. It is only after the discovery of vitamin U composite tablets of our laboratory, that a cure is possible for the purpose.

This medicine is a specialty for gastropathies: It provides for the organism with more proliferative methyl to promote the ulcerated part of gastro-intestinal tissue to accelerate healing. We strongly recommend to use our products TABLETS FARE-YOU COMPOSITA. Those who are effected with this kind of disease will be cured quickly, and the disease, will be soon eradicated.

There was no ingredient list in Chinese or English.

2. *Fritillaria Verticellata & Loquat*. Recommended in dry or spasmodic cough. Dose:

Half to one tablespoonful. Price: \$2.50. Made in Hong Kong.

The insert was only in Chinese.

3. *Ganmaoling Tablets*. (36 tablets) Made in Qixing Pharmaceutical Factory,

Guangzhou China. Manufacture Supervised by Guangdong Medicines & Health

Products Import & Export Corporation. Price: 60 cents.

Actions and Indications: Antipyrefic, antiphlogistic and antidotal. Applicable to

common cold and prevention of influenza, epidemic eicephalitis.

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⁷⁶ Field research conducted at the Nam Buk Hong pharmacy, 75 Harrison Avenue, Boston.

January 18, 1997.

Direction and Dosage: For adult, four tablets each, three times daily. Double dosage in severe cases, children decreased accordingly.

Prevention: Two tablets each, two times daily, to be taken continuously 3 days.

Ingredients: Flos Lonicerae: 4.85%; Flos Chrysanthemi Indici: 13.03%; Semen Viticis

Negundo: 13.03%; Radix Isatidis: 13.03%; Folium Et Ramulus Evodiae Leptae: 2 1.72%;

Radix Illicis Asprellae: 34.33%; Mentholum: 0.01%.

The insert stated in English and Chinese:

Ganmaoling a most effective preparation for the treatment of common cold and influenza, is extracted from selected Chinese medicinal herbs by means of scientific method. The chief actions of these medicinal ingredients of Ganmaoling are antipyretic, antidotal and antiphlogistic. The antipyretic efficiencies, is affording instantaneous relief with effects remarkably marvelous. Clinical observation has proved that Ganmaoling is excellent in cure and prevention of common cold and influenza. It is particularly valuable in the treatment of influenza with fever of different degrees during the onset of this disease. Usually, a dosage of four tablets can effectively put under control of all symptoms. Owing to its quick action and absence of undesirable side effects, both doctors and patients prefer to use this remedy.

4. *Naolutong Capsule.* (30 tablets) Naolutong [sic] is a new product for treatment of cerebral arteriosclerosis. Sequela of cerebral apoplexy and meningitis, cerebral palsy, spastic myeloplegia, amyotrophic lateral sclerosis. Price: \$5.50.

Dosage: 1-2 capsules each time, 3 times daily.

Made in China by the United Pharmaceutical Manufactory, Kwangchow.

The insert stated the above description in Korean as well. The rest of the insert was in Chinese, with an ingredient list printed in Chinese but not in English.

5. *Sumalin- Sugar Coated Tablets* (100 tablets).

Actions and Uses: Sumalin is remedy for prevention and treatment of coronary heart disease. It reduces elevated plasma cholesterol, triglyceride and B-lipoprotein levels and dilates coronary artery. It is used in atherosclerosis and other conditions characterized by high blood cholesterol level, such as angina pectoris, myocardial infarction, heart failure, hypertension, dizziness, headache, palpitation and breathlessness, etc.

Dosage and administration: Three times daily, 2 or 3 tablets each time after meal, or prescribe by doctor.

Storage: Preserve in dried place in well-closed container. Guangzhou MingXing Pharm. Fact.

Price: \$2.40.

The package insert was in Chinese only, and there was no ingredient list in English.

It is clear that the above prepackaged herbal medicines violate the provisions of the DSHEA and the statutory provisions mandated by the Food, Drug and Cosmetic Act for drugs. Many of these prepackaged Chinese herbal medicines come without ingredient lists, and sometimes the information is in Chinese only. The labels make fantastic claims about the diseases they treat, and it is difficult to believe that these brightly colored packages contain the treatments these serious diseases and conditions. Yet they are readily available for purchase at relatively low cost. These imported pre-packaged Chinese herbal medicines imported mainly from China, Hong Kong, and Taiwan, with its farfetched labeling and lack of ingredient lists, seem to be ripe for FDA regulation. In contrast, domestically manufactured Chinese herbal medicines found in a general health food store present a different picture entirely.⁷⁷ The Chinese herbal medicines manufactured in the U.S. make no health claims and list the ingredients. Hence there is a stark contrast between Chinese herbal medicines manufactured in the U.S. and compliant with DSHEA, and non-complaint imported medicines. One disturbing fact regarding this disparity is that the non-compliant herbal medicines are generally found in the Asian phannacies and stores, whereas general health food stores catering to the mainstream public stock the compliant domestically produced herbal medicines. This differentiation in the distribution of unregulated imported herbal medicines then, produces a situation where unregulated herbal medicines which are mislabeled and lacking in important information are floating freely in the Asian communities in this country, heightening the risk of endangering Asian-American health and safety.

⁷⁷Field research conducted at Cambridge Natural Foods, 1670 Massachusetts Avenue, Cambridge. January 18, 1997.

B. Popularity of Traditional Chinese Herbal Medicine in the United States Today

Within the past two decades, Americans have begun to take a greater interest in

traditional Chinese herbal medicine as well. An increasing number of consumers seem to have become disenchanted by impersonal and beleaguered physicians prescribing drugs

with strong side effects and so are turning to herbal teas, pills, extracts, and salves for

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help. Hence herbal teas, pills, and extracts can be found in drug stores for the treatment

of all manner of ailments, and herbs are now the fastest growing category in U.S.

drugstores.⁷⁹ In a New England Journal of Medicine study, the total projected out-of-pocket expenses for unconventional medicine⁸⁰ was \$10.3 billion, almost reaching the

level of out-of-pocket expenditures for all hospital care (\$12.8 billion) and almost half the total amount of out-of-pocket costs for all doctors' services (about \$23.5 billion.)⁸¹ The

same study found that in 1990 one out of three Americans had used an alternative therapy

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in the past year, herbal medicine being the most popular type employed. This

tremendous growth has meant big business for herbal manufacturers and dealers. In

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1980, herbal product sales amounted to \$167 million. It has skyrocketed since then,

⁷⁸Lauren Picker & Joshua McHugh, Herbal Medicine Goes Mainstream, Am. Lkalth, May 1, 1996.

⁷⁹ Smithsonian and ABC Sponsor Herbal Medicine Conference, Website of the Smithsonian Institute, (1995).

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Eisenberg defines unconventional medicine as medical practices that are not in conformity

with the standards of the medical community. These include acupuncture, chiropractic, massage therapy, herbal therapy, spiritual or religious healing by others, commercial weight-loss

programs, lifestyle diets, energy healing, folk remedies, and megavitamin therapy. David

Eisenberg, Unconventional Medicine in the United States—Prevalence, Costs, and Patterns of Use, 328 N. Eng. J. Med. 246-252 (1993).

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⁸³ Picker & McHugh, supra note 78.

with the U.S. herb industry having had an estimated \$2 billion in sales in 1995, and growing at an annual rate of about 20%.⁸⁴

Surprisingly, according to the New England Journal of Medicine study, the estimated number of visits to unconventional therapy practitioners outnumbered the

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number of visits to primary care physicians. The majority of those who used unconventional therapy did so to treat chronic, as opposed to life-threatening, medical

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conditions. About 1 in 4 Americans who see their physicians for a serious medical

condition may be using unconventional therapy, yet 7 out of 10 times the patient does not

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inform the doctor of the use of unconventional therapy. Unconventional therapies are

generally used in conjunction with conventional therapy, but about half of those who use unconventional therapy for their principal medical conditions do so without the supervision of a physician, a group estimated to number about 20 million Americans.⁸⁸

Many doctors are coming to believe that alternative medicine is in some cases a viable option as well. Wayne B. Jonas, director of the National Institutes of Health's

Office of Alternative Medicine, estimates that more than 50% of conventional physicians

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use or refer patients to alternative treatments. Although these studies do not specifically

focus on the prevalence of Chinese herbal medicine usage, they do indicate a trend towards greater acceptance of alternative medicines in general. But they also point to

⁸⁴Id.

⁸⁵Eisenberg, *supra* note 80.

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⁸⁹Marlene Cimons, *New Life for Old Remedies; No Longer Dismissed as Fringe Ideas, Such 'Traditional' Therapies as Acupuncture and Herbs Are Going Mainstream*, Los Angeles Times, Jan. 1, 1996.

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another danger: many people are using therapies without the oversight of a medical practitioner, and doctors are treating their patients without obtaining a complete medical history, a particularly hazardous situation because the doctors may be prescribing medicines with conflicting side effects and counterindications with the herbal medicines.⁹⁰

The doctors of tomorrow are being exposed early to traditional Chinese medicine. Thirty-four of the 125 medical schools in the U.S. offer courses in alternative medicine.⁹¹ At Case Western Reserve University School of Medicine in Cleveland, medical students can enroll in Chinese Qigong I and II, while students at the University of California at Los Angeles can go to its Center for East-West Medicine, a clinic for traditional Chinese healing techniques to brush up on their knowledge of Eastern therapies.⁹²

Biotechnology firms and pharmaceutical companies have not been immune to the growing interest in herbal medicines either, but such interest is not a new phenomenon. For centuries, plant-based folk remedies have formed the basis of Western medicine's pharmaceutical research.⁹³ The discovery of Digitalis's effectiveness in treating cardiac patients originated with a folk healer in Shropshire, England in the late eighteenth century.⁹⁴ However, with the appearance of synthetic compounds in the 1950's, ethnobotany- the study of the relationship between plants and people- faded as the leading source of pharmaceutical leads.⁹⁵ It is generally agreed that one quarter of

⁹⁰ Eisenberg, *supra* note 80.

⁹¹ Pueng Vongs, TCM Going Primetime, Website of Channel A, Sept. 17, 1996.

⁹² ~

David Taylor, Herbal Medicine at a Crossroads, ~ Vol. 104, No. 9, Sept. 1996. ⁹⁴Id.

⁹⁵Id.

Western medicines are derived from plants, although some believe the figure is actually closer to 60%.⁹⁶ Most Western plant-derived medicines, however, are created by isolating active ingredients, and not from the complex set of compounds that is found in most herbal remedies.⁹⁷ Recently, however, ethnobotany has reappeared, and scientists

trained to perform field work and bioassays made possible by technological advances can

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now test compounds against a wide array of diseases. These developments have

sparked investment in biodiversity prospecting, a wider approach than ethnobotany that carries out broad inventories of species in diverse ecosystems.⁹⁹ Within the realm of established Chinese medicines, however, the pharmaceutical company Pharmagenesis Inc., is developing new pharmaceuticals based on leads from traditional Chinese medicines.¹⁰⁰ And Pfizer Inc., under an agreement with the China Academy of

Traditional Medicine in Beijing, is also studying traditional Chinese herbs to find

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potential sources of new medicines.

There are two basic approaches to drug discovery: rational drug design and

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conventional random screening. Rational design-engineering new drug molecules requires knowledge of the drug target (like a receptor or enzyme), which although

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promising, has had limited payoffs. With random screening, synthetic chemicals or

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Alison Mack, *Biotechnology Turns to Ancient Remedies in Quest for Sources of New*

Therapies, ~ Jan. 6, 1997 at 1, 8.

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Tianhan Xue, *Exploring Chinese Herbal Medicine Can Foster Discovery of Better Drugs*,

Ih~..S.~knIjst, Vol. 10, #4, Feb. 19, 1996, at 9.

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natural products are indiscriminately tested for biological activity, which can be costly and time consuming.’~ Proponents of research into traditional Chinese medicine believe that in the area of drug discovery, developing new drugs based on leads from Chinese herbs is more effective than the conventional method of random screening because of the long history of clinical practice in Asia.’¹⁰⁵ The Chinese ethnopharmacopoeia has been

written down and is still taught in medical schools in China today, making it a living and

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vibrant system. In China, where almost 7,300 plants are used in Chinese herbal

medicine, about 60 new herb-derived drugs have been developed by Chinese scientists

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over the last four decades. Champions of investigating Chinese herbs for modern medical use point to cases where Chinese herbal therapies were effective when Western

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therapies were not. In a double-blind British clinical trial, a formula of Chinese herbs

produced significant results in cases of severe atopic eczema, which was previously

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resistant to conventional therapy. A controlled clinical trial in Japan showed that shosaiko-to, an extract of seven Chinese herbs, helps prevent liver cancer in patients with cirrhosis, marking the first treatment from any medical system that offers such benefits.⁰ In the U.S., several drugs of Chinese-herb origin are being commercially developed, including antimalarial drug qinghaosu derivatives’; huperzine A, for Alzheimer’s disease and trichosanthin, which combats HIV and has completed Phase II

105 Tianhan Xue, *Traditional Remedies, Modern Medicine*, Th~..S~knlist, Vol. 10, #2, Jan. 22,

1996, at 12.

’~Mack,supranote 100, at 1.

107 Xue, supra note 102, at 9.

108 Xue, supra note 105, at 12.

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M.P. Sheehan & D.J. Atherton, British Journal of Dermatology, 126:179-84, (1992). CiI~din Xue,supranote 105, at 12.

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clinical trials. A 1994 study published by the Office of Alternative Medicine cites more than nine published scientific studies, conducted mostly in Europe, confirming ginkgo's effectiveness in improving cognitive function and circulation and in reducing the risk of cardiovascular disease.³ The study also cites studies confirming benefits of milk thistle (*Silybum marianum*, used to prevent and repair liver damage) and saw palmetto (*Serenoa repens*, effective against benign prostatic hypertrophy).⁴ In 1990, a research team led by Sylvia Lee-Huang of New York University School of Medicine, Hao-Chia Chen at the National Institutes of Health, and Hsiang-fu Kung at the National Cancer Institute isolated a protein, MAP 30, from bitter melon, which has been used in China to treat infections, tumors, and immune disorders, and found it has multiple functions that are responsible for anti-HIV activity. These findings prompted William Paul, the director of AIDS research at NIH, to comment that the development must be vigorously pursued.⁶

The staunchest opponents of Chinese herbal medicine and other forms of alternative therapy claim that the increased prominence of alternative therapies is anti-science and part of a growing tide of irrationalism in the U.S. and Europe.¹¹⁷ They claim that the untestable belief systems upon which alternative therapies such as Chinese herbal

110 H. Oka et al., *Can J. Pharm. Med. Biol. Sci.*, 76:743-9, (1995). *Cited in* Xue, *supra* note 102, at 9. D.L. Klayman, *Am. J. Pharm. Med.*, 228:1049-55, (1985). *Cited in* Xue, *supra* note 102, at 9.

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S. Bornian, Chemical and Engineering News, Sept. 20, 1993, at 35-6. *Cited in* Xue, *supra* note 102, at 9.

113 Taylor, *supra* note 93.

114 *Id.*

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S. Lee Huang et al., Proceedings of the National Academy of Sciences, 92:8818-22, (1995). *Cited in* Xue, *supra* note 102, at 9.

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W. Paul, *J. Clin. Invest.*, 267:633-6, (1995). *Cited in* Xue, *supra* note 102, at 9.
117 Franklin Hoke, *Scientists See Broad Attack Against Research and Reason*, *Lab. Sci.*, Vol. 9, #14, July 10, 1995, at 1.

118 Id.

medicines are based attacks scientific inquiry by diverting public support for

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experimental research. Others who are less extremist contend there are serious concerns to be addressed regarding the safety of Chinese herbal medicines. Continued

research and development of new drugs from Chinese herbal medicines may be the best way of silencing such criticism. But in order to present pure compounds with demonstrable effects backed by clinical studies, one must first isolate the hundreds of compounds found in a single Chinese herbal remedy, which if not impossible, will take a very long time. In the meantime, people will still use unregulated Chinese herbal medicine, as the recent surge in its popularity has demonstrated. The dangers of imported medicine are greater because they do not conform to any FDA standards, while the U.S. produced herbal medicines are more careful about avoiding health claims and listing ingredients. But this does not mean that they can be assumed safe either. Because the domestically produced products do not make health claims, consumers tend to depend on store clerks for information about the different medicines, and the clerks may not be well-informed, let alone experts, about the uses of the different herbal products. Moreover, for manufacturers who wish to avoid the pre-approval process for drugs, marketing as a dietary supplement provides an attractive way to get their product on the market quickly, although the compound may still technically be a drug.

C. Dangers of Traditional Chinese Herbal Medicine

The increasing popularity of traditional Chinese medicines in the U.S. has caused a rise in the importation of potentially dangerous herbal medicines, mainly from Asia, but

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domestically manufactured Chinese herbal medicine pose dangers as well.⁹ Various factors can contribute to the dangerous use of Chinese herbal medicines. First, there are numerous different herbs that can be mixed in different combinations, so there is a sizable

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margin of error. Second, the labeling on prepackaged herbs does not always reflect

the contents nor do they provide appropriate directions and warnings about side effects or

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counterindications. Those who use alternative medicine along with conventional treatments may be harming themselves when the doctor is unaware of that fact and/or

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there is little known about the interaction between the medicines. And when directions

and warnings are provided, they are often written only in Chinese with imported

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medicines. Moreover, because imported products come from different places, the

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products are not necessarily uniform in quality or manufacturing. Foreign pharmaceutical companies often do not use rigid quality control standards nor do they test

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their products for purity or reliability. So the risk of contamination with toxic contaminants is a source of great concern. Herbal preparations can be directly toxic or toxic when taken in combination with other preparations.¹²⁶ Metals poisoning has been found on numerous occasions with Chinese herbal medicines. Recently, a chemist in the FDA's Seattle office analyzed a popular Chinese medicine known as rhino horn tea balls,

119 Evelyn Iritani, A Warning on Imported Herbal Medicine Lethal Toxins Found in Some Formulas, Seattle Post-Intelligencer, Nov. 9, 1994.

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Elaine Kang-Yum, Cross-Cultural Miscommunication, The Hastings Center Report, Vol.

26, No. 3, May 15, 1996.

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122 Rick Weiss, A Closer Look at Herbal Remedies; Federal Officials Examine Anecdotal Evidence on Safety, Usefulness, The Washington Post, Dec. 20, 1994.

123 Kang-Yum, supra note 120.
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125 Jacqueline Gazzella & John Pinto, Herbs: Use and Abuse, Current Concepts and Perspectives in Nu
Vol. 6, July 1987.

which was supposedly made up of herbs and ground rhino horn and used to treat people

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who had high fevers or had suffered a stroke. The chemist discovered that the

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medicine contained dangerously high levels of arsenic, lead, and mercury. Cases of lead poisoning caused by the ingestion of certain herbal products have been reported in

China, however, it was unclear whether the lead was an ingredient or a contaminant.²⁹ High levels of toxicity were also linked with use of Jin Bu Huan, a traditional Chinese

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herbal product used as a sedative and analgesic. A 1994 Journal of the American

Medical Association article reported that three Colorado children who had taken Jin Bu Huan manifested life-threatening central nervous system and respiratory depression.³¹

Subsequently, three women in Los Angeles were diagnosed with acute hepatitis attributed

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to the use of Jin Bu Huan. The JAMA report concluded that Jin Bu Huan or one of its

components was hepatotoxic. ³² Other imported Chinese herbal medicines have been found to contain various Western medicines, including barbiturates, nonsteroidal anti-inflammatory agents, antibiotics, diuretics, and narcotic pain relievers.³⁴ Proponents of Chinese herbal medicine maintain that small amounts of toxic metals such as lead and arsenic are used now and then to treat specific medical problems, and only for short

126 Id.

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Iritani, *supra* note 119. The rhino horn tea ball product was confiscated because it allegedly

contained endangered animal components. Id.

128 Id.

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G.M. Woolf et al., Jin Bu Huan Toxicity in Adults- Los Angeles, 1993, 271 JAMA 423 (1994).

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132 Id.

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134 Kang-Yum, *supra* note 120.

periods of time.¹³⁵ The danger, they argue, stems from people self-medicating and

ingesting toxic levels of these substances, or from taking products that are improperly

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mixed or mislabeled. Herbs, like drugs, they contend, should be approached with

caution, but given a chance to work.¹³⁷

The problem of misidentification is another related major source of concern, i.e., when by accident or through deliberate fraud, the plant product described on the label is different from that in the pill, capsule, or tincture.¹³⁸ The absence of an international agreement for common or Latin botanical names exacerbates matters.¹³⁹ An analysis of

24 herbal preparations of ginseng revealed the absence of ginsenosides, the active

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pharmacological constituent in ginseng. Instead, the ginseng preparations contained

incorrect species, altered mixtures of species, underweight products, and improper product labeling.¹⁴¹

Chinese herbal medicine claims its efficacy lies in the complex interaction between the various chemicals in the medicine, which can number in the thousands.¹⁴² Therefore it is difficult if not impossible to isolate pure ingredients and to obtain the reproducible results the FDA requires before approving a drug for even investigational status and testing.¹⁴³ Part of the difficulties in testing and maintaining purity arises from

135 Iritani, *supra* note 119.

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138 Weiss, *supra* note 122.

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140 Gazzella & Pinto, *supra* note 125.

141 *Id.*

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Arielle Emmett, Where East Does Not Meet West, Technology Review, Vol. 95, No. 8, at

50, 53 (1992).

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the use of whole herbs rather than individually isolated active ingredients.’ But supporters of Chinese herbal medicines assert that pure chemicals are not as effective as whole herbs.’⁴⁵ And there is also a possibility that individual active compounds may cause undesirable side effects without balancing chemicals present in traditional treatments. 146

III. Regulation of Traditional Chinese Herbal Medicine Under Current Laws

There are currently no regulations designed specifically for herbal medications in the United States. Under current FDA procedure, herbal medications may fall within the following regulatory categories: as foods, food additives, dietary supplements, or drugs. However, herbal medications generally come under the provisions for nutritional supplements because it is difficult for herbal medications to meet the FDA’s stiff drug standards and they do not conform exactly to the definitions of food or food additives.¹⁴⁷

A. History of Food and Drug Regulation in the U.S.: An Overview

America inherited a tradition of food regulation from England manifested in state laws as well as in federal laws promulgated with an aim towards regulating specific foods.’⁴⁸ In 1906 Congress enacted the Food and Drugs Act, the first federal statute to expansively prohibit the misbranding and adulteration of food. Though the 1906 Act

~Mack, *supra* note 100, at 1.

I.d.

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147 Edgar R. Cataxinos, Note, Regulation of Herbal Medications in the United States: Germany

Provides a Model for Reform, Utah Law Review 561 (1995).

148 Peter Barton Hutt, Government Regulation of the Integrity of the Food Supply, 4..Annua,1

Review of Nutrition 1 (1984); ~aJ~ Peter Barton Hutt and Richard A. Merrill, E~daIJ~ rug

Law: Cases and Materials (2d ed. 1991), at 1-4.

provided some protection against fraud, it had serious limitations, among them a lack of legal standards for foods, of restrictions on the use of poisons in drugs, and of fraudulent statements regarding drugs that are not in or on the food or drug package.¹⁴⁹ A tragedy in 1937 in which at least 73 people died as a result of taking the drug known as elixir

sulfanilamide opened many people's eyes and prompted Congressional action. The only legal basis for FDA intervention in that case was the fact that the preparation was

misbranded, since it was not a proper elixir.¹⁵⁰ To remedy these shortcomings, Congress passed the Food, Drug, and Cosmetic Act of 1938 (FDCA), which has been amended

many times since and currently regulates food and drugs.

Section 505 of the 1938 FDCA Act authorized the FDA to permit new drug applications (NDAs). Another tragedy, this time involving deformities in babies of

women who took thalidomide during their pregnancies, prompted Congress to act again. Congress responded by passing the Drug Amendments of 1962, which required the FDA to affirmatively determine that new agents have been demonstrated by substantial

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evidence to be effective, in addition to being safe. The effect of the 1962

Amendments was to hoist the onus of proving pre-market efficacy and safety onto the shoulders of the drug manufacturers.

B. Possible Classifications of Chinese Herbal Medicine

149 1917 Report of the USDA Bureau of Chemistry (1917); ~ Hutt and Merrill, supra note

148, at 11.

ISO David F. Cavers, The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its

Substantive Provisions, 6 Law & Contemporary Problems 2 (1939); s~..alsu Hutt and Merrill, supra note 148, at 476.

1933 Report of the Food and Drug Administration (1933); ~ Hutt and Merrill, supra note 148, at 11-13.

152 Hutt and Merrill, supra note 148, at 478.

Currently, there is no FDA definition for herbal medication, so regulation of traditional Chinese medicine may fall into one of the following four categories, depending on the use to which the product is put:

1. Food

The term food is defined as a) articles used for food or drink for man or other animals, b) chewing gum, and c) articles used for components of any such article.¹⁵³ Herbal medicine could be classified under a) or c). Under a food classification, the government bears the burden of proving the food is dangerous to the public health.¹⁵⁴ But there are other ways to reach the herbal manufacturer for a product that is classified a food: the FDA can challenge an herbal manufacturer for the introduction or delivery for introduction into interstate commerce of any food...that is adulterated or misbranded.¹⁵⁵ A food is deemed adulterated if it contains any poisonous or deleterious substance which may render it injurious to health.¹⁵⁶ The FDA can then instigate a seizure of the herbal medicine and prosecute the manufacturer if health problems arise from its use.¹⁵⁷ A food

is misbranded if its label is false or misleading, and the extent to which the labeling fails

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to reveal facts material to representations made is also taken into account. Again, this is grounds for the FDA to seize the product and prosecute.¹⁵⁹

2. Drug

21 U.S.C. § 321 (f).

¹⁵⁴ United States v. An Article of Food, 678 F.2d 735, 739 (7th Cir.1982).

¹⁵⁵ 21 U.S.C. § 331 (a).

¹⁵⁶ 21 U.S.C. § 342 (a)(1).

¹⁵⁷ 21 U.S.C. § 342 (a)(1), § 333 (a), § 334 (a) (1).

¹⁵⁸ 21 U.S.C. § 343 (a)(1), § 321 (n)..

¹⁵⁹ 21 U.S.C. § 334 (a).

Food additive is defined as any substance whose intended use results in or reasonably can be expected to result in its becoming a component of or otherwise affecting any food.¹⁶⁰ A food that has a food additive not found safe by the FDA or which has an approved additive in excess of the approved quantity is deemed adulterated,

and any additive in either of these categories is presumptively unsafe until it receives

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FDA approval. The approval process requires the filing of a premarket petition, so the

manufacturer basically bears the burden of proving safety.¹⁶²

The seemingly expansive language of the food additive definition is circumscribed by certain exceptions, including the following pertinent categories of substances: a) those that are generally recognized as safe; b) those that have been used in a substance before January 1, 1958, and has been found to be safe through either scientific procedures or experience based on common use in food; c) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, the Poultry Products Inspection Act or the Meat Inspection Act of March 4, 1907; or d) an ingredient meant for use in or intended for use in a dietary supplement.¹⁶³

For herbal manufacturers, it is important that their products fall outside the scope of the food additive definition, which requires undergoing costly testing and premarket approval procedures. Exception d), which was amended with the passage of the Dietary Supplement Health and Education Act of 1994, is the one most herbal manufacturers now

16021 U.S.C. § 321 (s).

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21 U.S.C. § 342 (a) (2) (C), 348 (c) (1) (A).

362 21 U.S.C. § 348 (b), (c).

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21 U.S.C. § 321 (s). There are other exceptions for pesticides, color additives, and animal drugs. Id.

use to escape the strictures of the food additive definition.^{IM} But they still remain subject to other food safety provisions.

3. *Drug*

A drug is defined as a) articles recognized in the United States Pharmacopoeia, Homeopathic Pharmacopoeia, or National Formulary; b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; c) articles (other than food) intended to affect the structure or function of the body (human

or animal); or d) articles intended for use as a component of any article specified in a), b),

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or c) above. In determining the intended use of a product for use as a drug, the FDA

considers representations made by the manufacturer in any forum, not just statements on the package label or insert.¹⁶⁶ The FDA has a number of times employed the broad definition of drug to regulate products that would have otherwise been subject to the food, device, or cosmetic provisions, in order to mandate premarket testing and approval,

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as required for all new drugs. The Supreme Court has upheld the FDA's authority to

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do so in order to accomplish its broad public health aims. Since the requirements for

The Ninth Circuit also limited the use of the food additive classification under exception b) for a Chinese herbal product which contained schizandra seed, traditionally used in China but which had not been a tested, commonly used food additive in the U.S. before 1958. The court in Fmali Herb. Inc. v. Heckler found that the common use language did not exclude evidence of the product's use outside the U.S. as probative of a food's safety, thereby limiting the FDA's regulation of traditional Chinese herbal products as a food additive. 715 F.2d 1385 (9th Cir. 1983).

165 21 U.S.C. § 321 (g) (1).

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Hutt and Merrill, *supra* note 148, at 386. Hutt and Merrill note that in an FDA regulatory letter regarding Favor Smokeless Cigarettes, the agency made use of company statements to the SEC. *Id.*

Id. at 385.

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Id. In United States v. An Article of Drug...Bacto-Unidisk, the Supreme Court found that the 'natural way' to draw the line 'is in light of the statutory purpose.' Since the patient will tend to derive less benefit and perhaps some harm from a particular antibiotic if, though the drug

drugs are generally stricter than those for foods or dietary supplements, manufacturers do not want their products to fall into this category.

a. Drug Approval Process

A drug can travel up the drug approval process through two channels. The first

path is if it is exempt by the grandfather clauses in either the FDCA or the 1962

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Amendment. If the drug can not be exempted through a grandfather clause, then the

manufacturer must go through the new drug approval process. Evaluating safety and effectiveness, and risk vs. benefit are the pivotal issues in FDA drug review. But it is a long and costly process, taking about 7 to 13 years and \$30-\$50 million to take a drug

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from research to marketing approval. There are three major stages, the first one being

preclinical research to identify whether the drug is sufficiently promising to study in

itself was properly batch-tested, it was not the proper antibiotic to use, it was entirely reasonable for the Secretary to determine that the discs, like the antibiotics they serve, are drugs and similarly subject to pre-clearance certification under § 507. An opposite conclusion might undercut the value of testing the antibiotics themselves, for such testing would be a useless exercise if the wrong disc were ultimately administered, even partially as the result of an unreliable disc... 394 U.S. 784 (1969).

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21 U.S.C. § 321 (p) (I). Under the FDCA, a drug shall not be deemed to be a 'new drug' if

at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use... Id. ~ Pub. L. No. 87-781, § 107 (c) (4), 76 Stat. 780, 789 (1962). Under the 1962 Amendments, a drug which (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section [321(p)] of the basic Act as then in force, and (C) was not covered by an effective application under section [355] of that Act, ... when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug. Id.

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Report of the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, The Food and Drug Administration's Process for Approving New Drugs, 96th Congress, 2d Session (1980). Cited in Hutt and Merrill, *supra* note 148, at 514-516. The exact length of the

drug review can vary since the FDA classifies investigational new drug applications (INDs) and new drug applications (NDAs) and assigns review priority based on the drug's chemical type and potential benefit. FDA Drug Approvals List, Website of the
FDA (1997).

humans, which takes from 1 to 4 years. If the drug passes the first stage, the

manufacturer files for an Investigational New Drug application (IND). If the FDA does not reject the IND, the manufacturer can begin the second stage, which consists of three

phases of clinical research designed to determine effectiveness in humans and to

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investigate side effects, which usually takes 4 to 6 years. In phase I the drug is

administered to humans with the primary purpose of detecting adverse effects and usually does not provide data on the efficacy of the drug on the disease it is meant to treat. If

the adverse effects do not so limit, the drug passes to phase II studies, which studies the

drug in patients with the disease it is designed to treat.¹⁷⁴ The objectives are to determine whether the drug has the desired therapeutic effect and if so at what dosage, and whether there are adverse effects.¹⁷⁵ If the drug is considered safe and effective, it passes into

phase III for more clinical study. In phase III, many more patients are studied, usually in

a clinical environment. The clinical, pharmacological and toxicological data for a drug

that passes at least two phase III trials is then collected in a New Drug Application (NDA) and submitted to the FDA Bureau of Drugs.¹⁷⁷

The information required in an NDA includes the results of the clinical tests; the drug's constitution—its components and composition; results of the animal studies; and

171 Id.

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173 Id.

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176 Id.

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how the drug functions in the body.¹⁷⁸ Documentation addressing how the drug is

manufactured, processed and packaged, particularly the quality controls employed, are

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also obligatory. Samples of the drug and its labels are necessary as well.

Effectiveness is then determined, especially on the basis of the controlled clinical trials, but the whole data bank is used to search for adverse effects.¹⁸¹ FDA reviewers then

evaluate the risk versus benefit of the drug.

Field inspectors are sent to make on-site checks of the investigators who performed the studies to ensure its validity, and since more foreign studies are being

accepted as evidence for drug approval, the FDA has been doing more foreign 182

inspections. If the FDA finds major discrepancies between their survey and the drug

sponsor's, more data may be required before approval can be granted. Drug review for a single product is a time consuming process, in recent years averaging about two years to complete.¹⁸³

For many traditional Chinese herbal manufacturers, the time and money needed to complete the new drug approval process is prohibitive. Moreover, the lack of patent

protection for plant-derived products acts as a monumental disincentive to undertaking

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the costly drug review process.

b. Over-the-Counter Drugs

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Dixie Farley, Benefit vs. Risk: How FDA Approves New Drugs, EDA~Qnsum~r, January

1995.

179 Id.

180 Id.

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183 d.

184 Cataxinos, supra note 147, at 574.

The 1962 Drug Amendments compelled the FDA to review all Over-the-Counter

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(OTC) drugs. To deal with an estimated 100,000 to one-half million OTC drugs, the

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FDA initiated rulemaking by therapeutic classes on an industry basis. This was done

through the implementation of monographs which established conditions under which a

category of OTC drugs were generally recognized as safe and effective and not

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misbranded. Any drug which had not received NDA approval or OTC monograph

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status could then be seized as an unapproved new drug. Consideration of homeopathic

drugs was explicitly deferred because they represented such a small volume of OTC

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products. However, traditional Chinese herbal medicine was not likewise exempted,

simply because it did not occur to the authors of the OTC monograph system to address the practice. **I 90**

One major obstacle for Chinese herbal medicines may be due to the complexity of its chemical compositions. To qualify for OTC monograph status, the drug is evaluated

as a whole, and the individual constituents do not need to be identified for purposes of determining safety and effectiveness.⁹⁹ But the FDA's OTC panels consist of experts

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who evaluate specific chemical compounds within that OTC category. The complex

185 Hutt and Merrill, *supra* note 148, at 588.

186 Over-the-Counter Drugs: Proposal Establishing Rule Making Procedures for Classification,

37 Federal Register 85 (January 5, 1972); *~iL~*in Hutt and Merrill, *supra* note 148, at 589.

187 Over-the-Counter Human Drugs Which Are Generally Recognized as Safe and Effective and

not Misbranded, 21 C.F.R. Part 330 § 330.10; *Cit~*in Hutt and Merrill, *supra* note 148, at 595.

188 Hutt and Merrill, *supra* note 148, at 590.

189 *~* Fed. Reg. 9464, 9466 (May 11, 1972); *~iI~*d.in Hutt and Merrill, *supra* note 148 at 596

(1991).

~ Conversation with Peter Barton Hutt, January 6, 1997.

'' Scott Martin, Note, Unlabelled Drugs as U.S. Health Policy: The Case for Allowing Health Claims on Medicinal Herb Labels; Canada Provides a Model for Reform, 9 Arimnn Journal of International and Comparative Law 545, 55-553 (1992).

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make-up of herbal medicines, which often have dozens of active ingredients, make it difficult even to identify the different compounds in Chinese herbal medicines. So although OTC review technically permits multiple compound drugs, the inability to identify the active chemical constituents in herbal medicines makes securing approval under the safe and effective standard generally unattainable.

Nonetheless, when Chinese herbal medicines are clearly labeled to prevent or treat disease, thereby making drug claims covered by the OTC monographs, the FDA has signaled its intention to challenge such products, even if they claim to be dietary

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supplements. For example, the FDA recently issued a warning letter to a company

whose energy boosting product contained the Chinese herbs ginseng, ma-huang, and guarana.⁹⁴ The FDA alleged that the manufacturer was making unlawful drug claims because the product's claims fell under the Stimulant Drug Products OTC Drug Monograph. ~ Commentators have argued that the DHEA creates a new regulatory scheme for dietary supplement products, and so if an OTC drug monograph has been established for an indication that is also a permissible dietary supplement statement under

section six of DSHEA, the monograph should be applicable only to products that do not

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meet the definition of a dietary supplement. Since DSHEA does not qualify the range

of statements that can be made by dietary supplements with any mention of potential

~ Robert Pinco & Paul D. Rubin, Ambiguities of the Dietary Supplement Health and

Education Act of 1994, 51 *£Qd.&Drug..LJ* 383 (1996), at 392.

194 *Id.*

195 *Id.*

196 *Id.*

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conflicts with the OTC drug review, certain OTC monographs may no longer be applicable to dietary supplements.¹⁹⁷

4. Dietary Supplements

The findings section of the 1994 Dietary Supplement and Health Education Act recognized that 50% of 260 million Americans regularly consume dietary supplements of vitamins, minerals, or herbs in an effort to improve their nutrition.¹⁹⁸ The passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA) has generally been heralded as a positive development for dietary supplement manufacturers and consumers. ~ Under DSHEA, a dietary supplement is defined as a product (other than tobacco) that is intended to supplement the diet and contains one or more of the following dietary ingredients: a vitamin; mineral; herb or other botanical; amino acid; dietary substance to increase total dietary intake; a concentrate, metabolite, constituent, extract, or combination of any of the aforementioned ingredients.²⁰⁰ It must also be in a traditional supplement dosage form, i.e. tablet, capsule, softgel, powder or liquid, or if not in such a form, it has to be labeled as a dietary supplement and it must not be represented for use as a conventional food or as a replacement for a meal or total diet.²⁰¹

The effect of this expanded definition is to ensure that the new protections of the DSHEA is applicable to a wide array of products, including those that the FDA deems as

297 Id.

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21 U.S.C. § 321 (9) (1994) (new section 201(9) of the FDCA).

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Stephen H. McNamara, Dietary Supplements of Botanicals and Other Substances: A New Era of Regulation, 50 Food and Drug Law Journal 341 (1995).

200 Pub. L. No. 103-417 § 3 (a), 108 Stat. 4327 (1994).

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Id. ~ Covington & Burling Memo, Dietary Supplement Health and Education Act of 1994, (October 12, 1994).

having no nutritional value. Another important effect of the new law is the explicit amendment of the FDCA to prevent the application of the food additive category to dietary ingredients or supplements. Before, the FDA had argued that substances added to dietary supplements were like substances added to any food product. If the substance

was not generally recognized as safe by experts, it was considered subject to regulation

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as a food additive. Filing a food additive petition required research and could cost

upwards of \$1,000,000 and usually took over five years before the FDA approved.² This meant that dietary supplements that contained ingredients that were viewed as food additives were illegal. DSHEA changes this frightening prospect for herbal drug manufacturers by preventing the term food additive from being used to regulate dietary supplements and their ingredients.

Under DSHEA, a dietary supplement is considered adulterated if it poses a significant or unreasonable risk of illness or injury, or an imminent hazard to public health or safety.²⁰⁵ The FDA has the burden of proving each element of adulteration.²⁰⁶ Another concession to dietary supplements made by DSHEA is with regard to health claims. Under the Nutrition Labeling and Education Act (NLEA), manufacturers were forbidden to print health claims on any food products, including dietary supplements,

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McNamara, *supra* note 199, at 342. The new definition also allows an article which has been marketed as a dietary supplement or a food before it has been approved as a drug, certified as an antibiotic, or licensed as a biologic by the FDA, to continue to be marketed as a dietary supplement unless the FDA publishes a regulation forbidding it. *Id.*

Id. at 343.

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Pub. L. No. 103-417 § 4 (f), 108 Stat. 4327 (1994).

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without FDA approval. DHSEA devised an exception to this by allowing certain statements to be made by a dietary supplement if the statement: a) claims a benefit related to a classical nutrient deficiency disease; b) describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans; c) characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function; or d) describes general well-being from consumption of a nutrient or dietary ingredient.²⁰⁸ The manufacturer has to substantiate that the statement is truthful and not misleading and the statement has to include the following text: This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.² The manufacturer then

has to notify the FDA no later than 30 days after the first marketing of the dietary

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supplement that such a statement is being made. The FDA has the burden of showing

that the dietary supplements are unsafe.²¹¹

The previous dividing line between drugs and dietary supplements was collapsed somewhat with Congressional passage of the DSHEA. Section six of DSHEA allows dietary supplement product labeling to include statements of nutritional support, however, the FDA still has premarket approval of certain drug claims. So if the supplement makes drug claims, or consists of a substance already regulated as a drug, then it will fall subject to the statutory requirements for drugs, which the dietary

²⁰⁷ McNamara, *supra* note 199, at 345.

²⁰⁸ FDCA § 343 (r) (6).

²⁰⁹ *Id.*

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FDA Panel Urges Controls for Herbal Ephedrine Products, *WiiL~.gaJ* 1, 9-5-96 WLN

9241, September 5, 1996.

supplement industry wants to avoid. The definition of drug includes articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals and articles (other than food) intended to affect the structure or any function of the body of man or other animals.²²² Therefore, if a dietary supplement manufacturer makes a claim that a dietary supplement diagnoses, cures, mitigates, treats or prevents disease, the dietary supplement will be subject to the premarket approval process of a drug. But the second clause, classifying articles that make structure or function statements as drugs, should no longer apply to dietary supplements because

DSHEA permits truthful structure and function statements, and states that dietary

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supplements are foods and not drugs. An unresolved issue is whether some dietary

supplement claims authorized by section six will fall under the drug definition.²²⁴ For example, if there is a product that claims to improve joint flexibility, can the FDA

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regulate it as a drug claiming to treat arthritis. Commentators have argued that based

on congressional intent and the statutory language of DHEA, the FDA should not characterize such legitimate structure/function claims and general well being claims as

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drugs. They argue that DSHEA was designed to encourage the dissemination of

truthful dietary supplement information to consumers without having to wait for FDA

212 21 U.S.C. s. 321(g)(1).

213 Pub.L. No. 103-417, s 10, 108 Stat. at 4331 (codified at 21 U.S.C. s 321(g)(1)).

224 Pinco & Rubin, supra note 193, at 390.

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pre-approval.²²⁷ Thus, if the reach of the FDA extends to implied claims, there is no limit to the FDA's control, because any claim will have an ostensible link to disease.²¹⁸

IV. Responses to Traditional Chinese Herbal Medicine

A. State and Federal Responses

The FDA has yet to contend specifically with the regulation of Chinese herbal medicine, but other government agencies and state legislatures have taken notice. The Office of Alternative Medicine (OAM) was created within the auspices of the National Institutes of Health to investigate an array of alternative treatments, including Chinese

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herbs. Almost \$8 million in funds earmarked by Congress for this purpose is being

apportioned to eight research centers over three years, which began in 1994.²²⁰

At the

University of Texas, research on biopharmacologic remedies is currently underway to test

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the effects of herbs and natural products on cancers. It is hoped that some of the

alternative techniques, if validated through clinical trials, will join mainstream

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medicine. Wayne Jonas, director of the OAM, points out that It's always been true

that the 'mainstream' of today is the 'alternative' of the past.²²³ Out of the 40 research

217 Id..

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219 Joy McIntyre, OAM Commences \$8 Million Investigation into Alternative Therapies, *1h*

S'nti, Vol. 10, #2, at 3 (1996).

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223 Id..

projects funded by the OAM between 1993 to 1995, five dealt with Chinese herbal medicine.²²⁴

Federal legislation is currently being considered that may ease the acceptance of non-traditional therapies like Chinese herbal medicine by respecting individual's choices regarding treatment. The Access to Medical Treatment Act, proposed in July 1995 by Senator Tom Daschle, would allow an individual to choose any medical treatment offered by a health care practitioner, including medical care that has not been approved, certified,

or licensed by the Secretary of Health and Human Services, as long as the patient is

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informed of the approval status. Though the Access to Medical Treatment Act has not

yet been enacted, the Department of Health and Human Services has established a set of

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regulations concerning Emergency Access to Promising Therapies. This applies only

to individuals who are in a life-threatening situation and unable to give their consent,

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however. Several conditions must be met first: available treatment must be unproven

or unsatisfactory; the risks and benefits of the experimental procedure have to be reasonable in light of the patient's medical condition and standard therapy; and the

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research into the experimental therapy can not be carried out otherwise. This set of

regulations was made possible by the FDA's issuance of final rules making it easier for promising experimental drugs and medical devices to be studied in those who are in life-

224 Corinna Wu, Yin and Yang, *Western Science Makes Room for Chinese Herbal Medicine*, ~ Sept. 9, 1995, at 172.

225 ~ 1035, 104th Cong., 2d Sess. (1995).

226 Don McLearn, *HHS Regulations Provide Emergency Access to Promising Therapies*,

Website of the FDA, P96-16 (Sept. 26, 1996).

227 Id.

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threatening situations and unable to give informed consent, and an NIH publication of an

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Emergency Research Consent Waiver applicable to all agencies of the HHS. These new policies were adopted in response to growing uneasiness that current regulations

were making research in emergency circumstances difficult at a time when such research

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was desperately needed. The willingness to accept non-traditional treatments in

emergency situations as demonstrated by these regulations opens the window for greater research into alternative therapies like Chinese herbal medicine.

Various states have also developed their own responses to the use of alternative

therapies generally and Chinese herbal medicine in particular. New York State amended its education and public health laws, so that of the eighteen physicians on the board for

professional medical conduct, now at least two are physicians who dedicate a significant

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portion of their practice to non-conventional medical treatments. Most importantly for

consumers, Chinese traditional medicine is also making its way onto the list of covered treatments under an increasing number of health maintenance organization plans.

Washington state now requires every health insurer to cover alternative treatments like acupuncture, massage therapy, naturopathy, and other forms of licensed natural health

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care. HMO's like Kaiser Permanente and insurers like Prudential are already covering

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acupuncture. It is estimated that by 1998, 25% of all managed care programs will

229 Id.

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231 N.Y. Public Health Law § 230 (McKinney's 1994).

232 Timothy Egan, Seattle Area Giving Natural Medicine a Chance to Come in from the Fringe, The New York Times, Jan. 3, 1996, at A10.

233 Vongs, *supra* note 91.

cover acupuncture. And a number of smaller health networks are covering traditional

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Chinese herbal medicines as well. As more mainstream physicians are prescribing

herbal treatments in conjunction with standard drugs, insurance companies, HMO's, and other health organizations are agreeing that doctor knows best, and are covering the costs.²³⁶

B. FDA Response to Traditional Chinese Medicine

Although Chinese herbal medicine can fall within the dietary supplement classification, products that make specific claims to treat, cure, or prevent a specific condition or ailment are technically drugs. Traditional Chinese herbal medicine, however, like herbal medicine generally, has largely gone unregulated by the FDA. Mr. William Goodrich, Chief Counsel of the FDA from 1939 to 1971 explained that the FDA stance towards Chinese herbal medicines during his tenure was that of a wait-and-see posture: the regulation of such drugs was not a priority unless they actually harmed

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people. He clarified this by saying that the FDA's budget in 1951 was about \$51

million, so given its limited resources, the FDA could not make the Chinese medicines a priority unless they were harming a sizable number of people. Mr. Goodrich noted that the number of complaints were small when he was in office. The FDA has commented on numerous occasions that its policy of only investigating products that have spurred

234 Id.

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236 Picker & McHugh, *supra* note 78.

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Telephone Interview with Mr. William Goodrich, former Chief Counsel, FDA, Jan. 14, 1997.

complaints is still standing. In a Federal Register notice issued after the passage of DHEA, the FDA stated:

In response to the DSHEA, FDA has also reassessed its general enforcement priorities with respect to dietary supplements. FDA advises that in enforcing the act with respect to these products, its primary focus is likely to be, as it always has been, on safety concerns. The agency advises, however, that its regulatory priorities are subject to adjustment in response to changing circumstances.²³⁹

However, when many deaths were reported in conjunction with the use of ephedrine containing products, instead of using its enforcement authority under DSHEA, the FDA issued a press release about the dangers of ephedrine, inaccurately claiming that it lacked the authority to regulate dietary supplements under DSHEA.²⁴⁰ Much attention had surrounded the ephedrine containing supplements which promise a natural high, and which are sold as weight loss aids, energy boosters, as well as an alternative to illegal

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drugs. These products, with such seductive names as Herbal Ecstasy, Ultimate

Xphoria, and Cloud 9, are derived from the Chinese herb ma huang, or ephedra.²⁴² Ma huang is one of the oldest herbs used in Chinese herbal medicine, and has been used to treat asthma, clear blocked sinuses and increase alertness and perception, although side effects like increased blood pressure have long been known.²⁴³ In recent years, the FDA stated that at least 17 deaths and over 600 reports of injuries have been associated with

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Randy Bimestefer, FDA on Chinese Patent Medicines in Taking the Mystery out of

Chinese Patent Medicines Website.

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60 Fed.Reg. 19,597 (Apr. 19, 1995).

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Pinco & Rubin, *supra* note 193, at 398.

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Associated Press, US May Move on 'Natural High' Herbs Ephedrine is at Issue in FDA Inquiry, The Boston Globe, Aug. 28, 1996.

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Delores Kong, Herbal Ecstasy Attracts FDA Scrutiny after Reports of Deaths, A Panel Will Decide Whether to Require Warning Labels for Supplements Made From Ma Huang, a Chinese Herb with Ephedrine, The Fort Worth Star-Telegram, Feb. 18, 1996.

243 Id.

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the use of ephedrine supplements. An FDA panel investigating ephedrine products eventually called for curbing the sale of ephedrine products and proposed also to reduce dosage recommendations, include label warnings, and control manufacturing. But some have alleged that the FDA refrained from using its enforcement powers more vigorously so that Congress would become convinced that stricter dietary supplement legislation was

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necessary. It also indicates that the agency's need to proceed on a case-by-case basis

slows the regulatory process, although the FDA has tried to combat that by publishing consumer information on the broader issues of how to select alternative treatments.²⁴⁶

Chinese medicines that have elicited specific complaints or which consist of components under investigation by the FDA are not allowed to be imported. Mr. Sam Fine, former Associate Commissioner for Compliance, commented that he remembered

discussion about the dangers of Chinese herbal medicines at the FDA, especially when

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combined with American drugs. The FDA sought to control the import of misbranded

drugs or drugs with false and misleading claims by working jointly with the Bureau of Customs and stopping imports at the border, mainly through the issuance of import alerts. But Mr. Fine echoed Mr. Goodrich's report that not many complaints were made. One such recent import alert, updated December 18, 1996, called for the automatic detention of Chinese herbal medicines because the products were new drugs without approved new drug applications and the labeling lacked adequate directions for its intended use.²⁴⁸

24-4 Associated Press, *supra* note 241.

245 Pinco & Rubin, *supra* note 193, at 398.

246 David Taylor, *supra* note 93.

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Telephone Interview with Mr. Sam Fine, former Associate Commissioner for Compliance, FDA, Jan. 14, 1997.

²⁴⁸Chinese Herbal Medicines, Import Alert, Sept. 18, 1996, Website of the FDA.

When the product was accompanied by drug claims, it was subject to both charges, and

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when not accompanied by drug claims, just the latter. It noted as the reason for the alert that Chinese herbal medications have a history, dating back to 1974, of containing

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strong prescription drugs. The import alert stated that the medicines originated from

several sources, and usually enter the country by air mail shipments to health food stores,

oriental food stores, novelty shops, and individual consumers, with it occasionally being

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sold door-to-door. Actual enforcement against imported medicines already in the

country is rarer, though in 1991 the FDA worked with the Federal Trade Commission to

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stop a New York firm's false advertising in Chinese. After receiving numerous complaints, the FDA warned the importer that the products were considered drugs and so

they either had to stop making the claims or go through the appropriate channels for a

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drug application.

Dr. Lori Love, a doctor in the FDA's Center for Food Safety and Applied Nutrition remarked that they do seriously evaluate some herbal products that have

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received adverse reports. The FDA focuses its limited resources on looking into the most serious complaints and on issuing import bans on herbal products found to be

dangerous, and so the FDA has stepped in to enforce safety and adulteration guidelines

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under DSHEA. But as the ephedrine controversy demonstrated, taking actions to stop

249 Id.

250 Id.

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Igor Cerny et al., Reports from the Field, EDA&~nsum~r, April 1991, at 43.

253 Id.

254 Iritani, supra note 119.

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products proven to be dangerous can be time consuming, and many injuries and deaths can occur in the meantime.

Part of the answer seems to lie in what the FDA is doing now with foreign pharmaceutical manufacturers. The FDA is working on testing herbal medicines in conjunction with foreign companies before there are any signs of trouble. Testing on purified forms of active compounds found in Chinese herbs have been occurring for years now, such as when the FDA approved testing on humans of an experimental AIDS drug derived from the root of a Chinese cucumber plant in 1989.²⁵⁶ But recently the FDA has granted approval to foreign companies to run trials not of isolated purified compounds, but of Chinese herbal medicines entire. The Japanese pharmaceutical manufacturer Tsumura & Co. garnered approval to run phase II clinical trials followed by a large-scale

double-blind comparative trial of a Chinese herbal medicine used for treating chronic

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rheumatoid arthritis. The FDA has also begun to grant approval of Chinese manufactured herbal medicines. Hainan Hengxin Pharmaceutical Co. has received FDA

approval for its ginseng pills, a preparation made from ginseng and other Chinese herbs

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which is used to stimulate the immune system. It has signed a supply contract with a

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U.S. corporation for \$3.5 million.

256 FDA Approves Testing on Humans of AIDS Drug from Cucumber Plant, *HQusi~a Uir~nkk*, April 28, 1989.

257 FDA Grants Tsumura Approval to Run Trials of Chinese Herbal Medicine, *~Qmlin~.flahIy*

News Biotechnology and Medical, Dec. 17, 1991.

258 *Hainan Herbal Medicine Wins Approval of U.S. FDA*, *Comline Daily News Biotechnology an4.M~dk~l*, Jan. 8, 1997.

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V. Models for Reform

It is apparent that the FDA has begun to recognize the importance of taking steps ex ante to safeguard the public health with regard to the consumption of Chinese herbal medicine. But these measured steps are a far cry from a plan of action for the FDA. A

1994 Office of Alternative Medicine report noted that the current regulatory mandate puts

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the FDA in a difficult position. It is expected to 'protect the public' but neither has the

expertise nor the resources to assess the catalogue of global herbal medicines.²⁶ The study suggests that instead of expecting the FDA to be an omnipotent protector, Congress should legislate a more educational, informational role for the FDA, allowing

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for such features as certification of herbal content and potency on labels. Other nations

have taken similar steps with regard to the regulation of herbal medicines, therefore it may be helpful to look at two models, one European, the other North American, to observe how others are approaching this issue and to perhaps glean insight into how the U.S. can better handle the matter.

1. Germany

Germany provides a useful model for reform with its long history of herbal medicine use. Considerable research is done through universities or in-house by

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pharmaceutical companies. The Bundesgesundheitsamt then examines the research

and other sources of relevant information such as published reports and pharmacological

260 Taylor, *supra* note 93.

261 *Id.*

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263 Varro E. Tyler, *Phytomedicines in Western Europe: Potential Impact on Herbal Medicine in*

the United States, 534 ACS SYMP. SERIES 25 (1993) at 27. *See also* Cataxinos, *supra* note 147, at 578.

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investigations before coming to a decision about the herbal medicine. Because the Bundesgesundheitsamt evaluates research literature, pharmaceutical manufacturers are

encouraged to enter into research endeavors to advance a positive assessment of their

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product. In the U.S., the costs of the drug approval process substantially diminish the

incentive of pharmaceutical companies to conduct the research and to invest in the drug approval process. The difficulty in patenting herbal medicines has also been cited as a major disincentive for pharmaceutical companies. But in Germany, since approval of herbal drugs depends on clinical and pharmacological literature as well as on the outcome of studies, the process has been characterized as requiring reasonable certainty rather than the absolute proof of safety and efficacy required by the FDA.²⁶⁶ The

Bundesgesundheitsamt created a special committee to regulate herbal medicines, Commission

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E. Commission E makes its determinations based on primarily bibliographic information, experimental results, and other literature that sheds light on the benefits and

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drawbacks of the medicine. After surveying all the data, Commission E issues a

benefit-to-risk ratio known as a monograph, which gives either a positive or negative assessment of the product, a positive assessment resulting in marketing approval.²⁶⁹

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Id. at 26.

267 Cataxinos, *supra* note 147, at 579.

268 Paul Bergner, German Evaluation of Herbal Medicines, *ikrkalgram*, Winter 1994 at 17.

See Cataxinos, *supra* note 147, at 580-1.

269 K. Keller, Results of the Revision of Herbal Drugs in the Federal Republic of Germany with a

Special Focus on Risk Aspects, 13 *Zeitschrift Fur Phytotherapie* 116, at 117 (1992); Paul Bergner, German Evaluation of Herbal Medicines, *Herbalgram*, Winter 1994 at 17. *See* Cataxinos, *supra* note 147, at 581.

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Commission E has published 285 monographs since its inception in 1978. Of those published, sixty-six percent document risk considerations, and of that group, fifty-eight monographs had a negative benefit-to-risk ratio because of insufficient evidence of

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efficacy, and so were banned from the market. Sixty-three monographs noted contraindications based on possible allergic reactions, while twenty-four restricted use

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during pregnancy or lactation. Seven monographs contraindicated use for those with

inflammatory kidney disease and fifteen contraindicated use for those with gallstones.²⁷³

The evaluation of side effects is a key feature of the monographs, and thirty-five

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monographs limit the period of use to curtail side effects. Herbal medicines have been

banned by Commission E for being linked to unacceptable terminal risks, such as a ban on all herbal medications containing the constituent aristolochic acid, a known carcinogen.²⁷⁵

The situation in Germany prior to the Commission E monographs was somewhat similar to the situation in the U.S. today. There were conflicting opinions over whether the herbal medicines were safe or unsafe, and the German government did not feel it had

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Bergner, *supra*.note 268. *~it~din Cataxinos*, *suprn* note 147. Under Germany's Medicines Act of 1976, herbal products marketed prior to the Act received provisional marketing authorization until April 1990, whereupon manufacturers had to present documentation confirming their product's safety and efficacy under the new standards. 14. at 579.

271 Paul Bergner, *supm* note 268. *£iI~din Cataxinos*, *supr~* note 147.

272 *Id.*.

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275 *Id.* ~ The Federal Health Office [through Commission E] Withdrew the Approval of

about 240 Herbal Drugs Containing Aristolochic Acid, quoted in K. Keller, Results of the Revision of Herbal Drugs in the Federal Republic of Germany with a Special Focus on Risk Aspects, 13 Zeitschrift Fur Phvtotherapie 116, at 118 (1992). *£iI~din Cataxinos*, *supra* note 147, at 583-4.

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sufficient authority to present any one view as definitive. But consumers needed some protection from drugs which were dangerous or misleading. The use of Commission E monographs has allowed for the expression of varied views, making for a more informed populace.²⁷⁷

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Canada provides an alternative model for reform of herbal medicine regulation. Canada regulates medicinal herbs as drugs, regardless of the claims made.²⁷⁸ And

Canadian law requires medicinal herb labels to contain health claim information for **279** cifically, labels on Canadian herbal medicinal products must state

consumers. Spe

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indications for use and dosage requirements. One important difference in the drug

approval procedure for non-prescription drugs in Canada is that each drug receives its own Drug Identification Number (DIN). A new drug application includes detailed information about the product's composition and dosage, pharmacological or other

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medical reference sources, and a draft label. Each drug, regardless of the number of active ingredients, receives its own DIN. Therefore, medicinal herbs can be approved for

use despite chemical complexity. This is in sharp contrast to the FDA approval process,

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Bergner, *supra* note 268, at 64. S¹ K. Keller, *supra* note 275, at 120. B[~]thsi^l~din

Cataxinos, *supra* note 147, at 585.

²⁷⁷ Cataxinos, *supra* note 147, at 585.

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See HPB I.L. No. 771, at 2-5 (Jan. 5, 1990) (Can.). ~i^l~din Scott Martin, Unlabelled 'Drugs' as U.S. Health Policy: The Case for Allowing Health Claims on Medicinal Herb Labels; Canada Provides a Model for Reform, 9 *Ariz. J. Int'l. & Comp. Law* 545, at 546.

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HPB LL. No. 771, at 4 (Jan. 5, 1990) (Can.). £it[~]din Martin, *supra* note 278, at 546-7.

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281 Food and Drug Regulations C.01.014.1, C.10.003 (Can.), referred to in HPB I.L. No. 771, Appendix A (Jan.5, 1990) (Can.) Cit[~]in Martin, *supra* note 278, at 571.

which requires reproducible results and does not allow for the approval of complex chemical compounds like those found in traditional Chinese herbal medicines.

In Canada, medicinal herbs are classified in two categories: the first is for herbs

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listed in pharmacological reference books, and is adequate for DIN status. These herbs

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are what would be thought of as drugs in the common sense. The second category

consists of herbs that may not have been used in Canada but have traditionally been used

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elsewhere in the world. The Health Protection Branch, Canada's equivalent of the

FDA, includes empirical or anecdotal testimony of the herb's efficacy as a basis for DIN

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approval. The acceptance of such non-scientific criteria is similar to one of the

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generally recognized as safe (GRAS) exceptions to food additives in the U.S. The

Traditional Folk Medicines category has brought about better labeled herbal products, but

the scope of permitted uses for the herbal products is limited to treating minor, self-

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limiting conditions, much as OTC drugs are used in the U.S. Hence, sometimes a

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product that is not allowed in Canada can be found in the U.S.

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In Canada, as well as in Germany, the history of an herbal drug's prior use can be used as evidence of its safety. And in other European countries, traditional use of herbal

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HPB I.L. No. 771, at 3 (Jan. 5, 1990) (Can.) £it~din Martin, supra note 278, at 571-2. **283** Martin, supra note 278, at 572.

284 H.P.B. I.L. No. 771, at 2-3 (Jan. 5, 1990) (Can.). Cit~din Martin, supra note 278, at 572.

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In the US, evidence of widespread use of a food additive prior to 1958 is allowed as evidence

to demonstrate that it is generally recognized as safe. Martin, *supra* note 278, at fn 232.

287 HPB I.L. No. 771, at 3 (Jan. 5, 1990) (Can.). *See* also Martin, *supra* note 278, at 572.

288 Martin, *supra* note 278, at 572.

289 Xue, ~ note 102, at 9.

290 Taylor, *supra* note 93.

291 *Id.*

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drugs is usually deemed sufficient evidence of its safety and efficacy. France officially

recognizes more than 200 medicinal plants and provides specifications regarding their

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sale. An April 1995 article in the British Medical Journal suggested special licensing

of herbal medicines for treatment of minor illnesses, stating that the public health is not well served when the strict application of conventional criteria to herbal medicine products leaves most such products outside the purview of regulatory control.²⁹¹ Although one could argue that these models allow too much latitude to consumers, leaving problems to arise on the market as consumers use these products, in the mistaken belief that the herbal medicines have in some way been proven totally safe by passing the government approval process. But that is not much worse than the state of herbal medicines in the U.S. today. The FDA works on a passive system, and only when problems arise and formal complaints filed can any action be undertaken against the

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manufacturer. The establishment of a separate office to evaluate traditional Chinese

herbal medicines and then to issue monographs gives consumers the information needed to make better informed decisions, and will prevent purchases of herbal medicines based on hearsay and speculation. The law as it stands today discourages information dissemination lest the product fall under regulation as a drug, and though DSHEA gives greater deference to dietary supplement manufacturers in some of its labeling claims, it still falls short of providing the information needed by the consuming public to make informed decisions about Chinese herbal medicine.

Chinese herbal medicines, if continued to be regulated under dietary supplements, will need to substantiate structure/function statements and general well-being claims.²⁹³

The standard should not be as high as those for drugs, given the disincentives already

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described, such as the inability to patent herbal medicines. Product-specific substantiation may be one solution, where each product has to prove its effectiveness for

its intended use through product-specific studies, unless the product is very similar to

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another that has already been proven effective.

There are other measures that could be adopted given the FDA's limited resources. Instead of waiting for a series of complaints and then taking action, which might come too late for many victims, as was the case with the ephedrine products, perhaps the FDA could act sooner to target and seize non-compliant Chinese herbal medicines on a small scale, thereby generating and using various means of publicity to disseminate information about the product's dangers. Licensing of Chinese herbal practitioners and pharmacists, as well as accreditation of schools teaching Chinese herbal medicine are other steps that would help ensure the health and safety of the consuming public.

The FDA's willingness to act will depend on how high it places Chinese herbal medicines on its already long list of priorities. FDA's agreements with foreign pharmaceuticals like Tsumura & Co. and Hainan Hengxin Pharmaceutical Co. seem to

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Serena K. Lee, To Regulate or Not to Regulate Herbal Medicines, *Nth~LA~ia.n ≥N~kly*, Nov. 27, 1995.

293 Pinco & Rubin, *supr~* note 193, at 394.

294 *Id.*

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demonstrate, however, that the FDA has begun to recognize the impact of Chinese herbal medicine on America's health and pocketbook. By taking a more proactive stance in exercising its enforcement powers, and by instituting a separate office with a monograph system similar to the European and Canadian models, consumers will no longer be left to guess what is in the Chinese herbal medicines they are taking.